SENATE MOTION

MR. PRESIDENT:

I move that Engrossed House Bill 1004 be amended to read as follows:

Page 104, between lines 24 and 25, begin a new paragraph and insert:

"SECTION 104. IC 12-7-2-22, AS AMENDED BY P.L.272-1999, SECTION 10, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: Sec. 22. "Board" means the following:

(1) For purposes of IC 12-10-10 and IC 12-10-11, the community and home options to institutional care for the elderly and disabled board established by IC 12-10-11-1.

(2) For purposes of IC 12-12-7-5, the meaning set forth in IC 12-12-7-5(a).

(3) For purposes of IC 12-15-35, the meaning set forth in IC 12-15-35-2.

(4) **For purposes of IC 12-15-35.5, the meaning set forth in IC 12-15-35.5-1.**

(5) For purposes of IC 12-17-2-36, the meaning set forth in IC 12-17-2-36(a).".

Page 106, between lines 30 and 31, begin a new paragraph and insert:

"SECTION 106. IC 12-15-35-28 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: Sec. 28. The board has the following duties:

(1) The adoption of rules to carry out this chapter, in accordance with the provisions of IC 4-22-2 and subject to any office approval that is required by the federal Omnibus Budget Reconciliation Act of 1990 under Public Law 101-508 and its implementing regulations.

(2) The implementation of a Medicaid retrospective and prospective DUR program as outlined in this chapter, including the approval of software programs to be used by the pharmacist for prospective DUR and recommendations concerning the provisions of the contractual agreement between the state and any

other entity that will be processing and reviewing Medicaid drug claims and profiles for the DUR program under this chapter.

(3) The development and application of the predetermined criteria and standards for appropriate prescribing to be used in retrospective and prospective DUR to ensure that such criteria and standards for appropriate prescribing are based on the compendia and developed with professional input with provisions for timely revisions and assessments as necessary.

(4) The development, selection, application, and assessment of interventions for physicians, pharmacists, and patients that are educational and not punitive in nature.

(5) The publication of an annual report that must be subject to public comment before issuance to the federal Department of Health and Human Services and to the Indiana legislative council by December 1 of each year.

(6) The development of a working agreement for the board to clarify the areas of responsibility with related boards or agencies, including the following:

(A) The Indiana board of pharmacy.

(B) The medical licensing board of Indiana.

(C) The SURS staff.

(7) The establishment of a grievance and appeals process for physicians or pharmacists under this chapter.

(8) The publication and dissemination of educational information to physicians and pharmacists regarding the board and the DUR program, including information on the following:

(A) Identifying and reducing the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care among physicians, pharmacists, and recipients.

(B) Potential or actual severe or adverse reactions to drugs.

(C) Therapeutic appropriateness.

(D) Overutilization or underutilization.

(E) Appropriate use of generic drugs.

(F) Therapeutic duplication.

(G) Drug-disease contraindications.

(H) Drug-drug interactions.

(I) Incorrect drug dosage and duration of drug treatment.

(J) Drug allergy interactions.

(K) Clinical abuse and misuse.

(9) The adoption and implementation of procedures designed to ensure the confidentiality of any information collected, stored, retrieved, assessed, or analyzed by the board, staff to the board, or contractors to the DUR program that identifies individual physicians, pharmacists, or recipients.

(10) The implementation of additional drug utilization review with respect to drugs dispensed to residents of nursing facilities

shall not be required if the nursing facility is in compliance with the drug regimen procedures under 410 IAC 16.2-3-8 and 42 CFR 483.60.

(11) The consultation and development with the office of a preferred drug formulary in accordance with IC 12-15-35.5.

SECTION 107. IC 12-15-35.5 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]:

Chapter 35.5. Preferred Drug Formulary

Sec. 1. As used in this chapter, "board" refers to the drug utilization review board established by IC 12-15-35-19.

Sec. 2. (a) The office in consultation with the board may develop, establish, and implement a preferred drug formulary in accordance with 42 U.S.C. 1396r-8.

Sec. 3. (a) In establishing the formulary under section 2 of this chapter, the office may negotiate supplemental rebates from manufacturers that are in addition to rebates required under Title XIX of the Social Security Act.

(b) A supplemental rebate under subsection (a) must be at least ten percent (10%) of the average manufacturer price (as defined in 42 U.S.C. 1936) on the last day of a quarter unless:

(1) the federal rebate; or

(2) the federal rebate plus the supplemental rebate;

is more than twenty-four percent (24%) of the average manufacturer price.

(c) A supplemental rebate negotiated by the office under this chapter does not have an upper limit.

Sec. 4. The board or the office may determine that a specific product that is a brand name drug or generic drug is competitive at a lower rebate percentage.

Sec. 5. (a) An agreement by a drug manufacturer or labeler to pay the minimum supplemental rebate shall guarantee that the specific product of the manufacturer or labeler will be considered by the board and the office for inclusion in the preferred drug formulary; however, a product of the drug manufacturer or labeler that agrees to pay the minimum supplemental rebate for a product is not guaranteed to be placed on the preferred drug formulary.

(b) A drug that is generally prescribed for the treatment of a mental illness (as defined in the most recent publication of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders) must be included in the preferred drug formulary.

Sec. 6. Except as provided in section 5(b) of this chapter, a determination by the office of the drugs included on the preferred drug formulary must be based on the following:

(1) The clinical efficacy of the drug.

(2) Recommendations by the board.

(3) The price of competing products less the amount of any federal or state rebate.

Sec. 7. The office may contract with a person to conduct negotiations for supplemental rebates.

Sec. 8. The prior authorization process under this chapter must do the following:

(1) Ensure real-time receipt of requests by:

(A) telephone;

(B) voice mail;

(C) facsimile;

(D) electronic transmission; or

(E) mail;

on a twenty-four (24) hour basis, seven (7) days a week.

(2) Provide for an in-person response to emergency requests by a prescriber with telephone answering queues that are not more than ten (10) minutes.

(3) Use a system for authorization in an emergency in which:

(A) the authorization is responded to in not more than four (4) hours from the time the program or participating health benefit plan receives the request; or

(B) authorization for a seventy-two (72) hour supply of the drug may be provided to the individual for whom the prescription is written.

Sec. 9. The office may adopt rules under IC 4-22-2 necessary to implement this chapter.".

Page 107, between lines 32 and 33, begin a new paragraph and insert:

"SECTION 110. IC 16-18-2-32.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: **Sec. 32.5. "Average wholesale price", for purposes of IC 16-42.5, has the meaning set forth in IC 16-42.5-1-2.**

SECTION 111. IC 16-18-2-197.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: **Sec. 197.5. "Labeler", for purposes of IC 16-42.5, has the meaning set forth in IC 16-42.5-1-3.**

SECTION 112. IC 16-18-2-216 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: Sec. 216. (a) "Manufacturer", for purposes of IC 16-42-19, ~~and~~ IC 16-42-21, **and IC 16-42.5,** means a person who, by compounding, cultivating, harvesting, mixing, or other process, produces or prepares legend drugs. The term includes a person who:

(1) prepares legend drugs in dosage forms by mixing, compounding, encapsulating, entableting, or other process; or

(2) packages or repackages legend drugs.

(b) The term does not include pharmacists or practitioners (as defined in section 288(a) and 288(c) of this chapter) in the practice of

their profession.

SECTION 113. IC 16-18-2-318.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: **Sec. 318.5. "Retail pharmacy", for purposes of IC 16-42.5, has the meaning set forth in IC 16-42.5-1-4.**

SECTION 114. IC 16-18-2-320.8 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: **Sec. 320.8. "Rx program", for purposes of IC 16-42.5, refers to the Rx program established by IC 16-42.5-2-1.**

SECTION 115. IC 16-18-2-374 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]: Sec. 374. (a) "Wholesaler", for purposes of IC 16-42-11, has the meaning set forth in IC 16-42-11-3.

(b) "Wholesaler", for purposes of IC 16-42-19, ~~and~~ IC 16-42-21, **and IC 16-42.5,** has the meaning set forth in IC 16-42-19-10.

(c) "Wholesaler", for purposes of IC 16-41-32, has the meaning set forth in IC 16-41-32-13.

SECTION 116. IC 16-42.5 IS ADDED TO THE INDIANA CODE AS A **NEW** ARTICLE TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2002]:

ARTICLE 42.5. FAIR PRICING FOR PRESCRIPTION DRUGS

Chapter 1. Definitions

Sec. 1. The definitions in this chapter apply throughout this article.

Sec. 2. "Average wholesale price" means the average of the following:

(1) The wholesale price assigned by a drug manufacturer to a specific commodity that is listed in a nationally recognized drug pricing file.

(2) Supplemental rebates for Medicaid programs above those required under 42 U.S.C. 1396r-8.

(3) Discount prices or rebates for the Indiana prescription drug program established under IC 12-10-16.

(4) Rebates and discounts negotiated for other state programs that pay for or acquire prescription drugs.

Sec. 3. "Labeler" means a person or an entity that:

(1) receives prescription drugs from a manufacturer or wholesaler;

(2) repackages those drugs for later retail sale; and

(3) has a labeler code from the federal Food and Drug Administration under 21 CFR 207.20.

Sec. 4. "Retail pharmacy" means a retail pharmacy or another business that is licensed to dispense prescription drugs in Indiana and either:

(1) participates in the state Medicaid program; or

(2) voluntarily agrees to participate in the Rx program.

Chapter 2. General Provisions

Sec. 1. The Rx program is established to provide discounted prescription drug prices to the following Indiana residents:

(1) Uninsured persons.

(2) Underinsured persons.

(3) Medicare recipients.

(4) Insured or self funded employee welfare benefit plans described in the federal Employee Retirement Income Security Act (29 U.S.C. 1001 et seq.) that provide prescription drug benefits to residents of Indiana.

Sec. 2. (a) Subject to subsection (b), an Indiana resident is eligible to participate in the Rx program if the resident meets any of the following criteria:

(1) The resident is eligible for Medicare.

(2) The resident has a net family income of not more than four hundred percent (400%) of the federal poverty level.

(3) The resident has a single wage earned income of not more than three hundred percent (300%) of the federal poverty level or the resident is more than sixty (60) years of age.

(b) An Indiana resident is ineligible for the Rx program if the individual:

(1) is eligible for Medicaid;

(2) has prescription drug coverage under any health insurance plan or public assistance program in which the prescription drug coverage is equal to or greater than the Rx program benefits; or

(3) is eligible for the Indiana prescription drug program established by IC 4-12-8-2 and sufficient funds exist in that program to allow the individual to participate in the program. If insufficient funds result in the eligibility of an individual for the Rx program and sufficient funds later become available under the Indiana prescription drug program, an individual who is eligible for that program becomes ineligible for the Rx program and must transfer to the Indiana prescription drug program.

(c) The state department shall establish simplified procedures for determining eligibility and issuing Rx program enrollment cards.

(d) The state department shall undertake outreach efforts to build public awareness of the Rx program and maximize enrollment.

(e) The state department may adjust the requirements and terms of the Rx program to accommodate any new federally funded prescription drug program.

Sec. 3. The state department shall submit a report on the enrollment and financial status of the Rx program to the legislative council before January 1 of each year.

Sec. 4. The department may adopt rules under IC 4-22-2 to implement this article.

Sec. 5. The state department shall do the following in implementing the Rx program:

(1) Coordinate with other governmental programs.

(2) Take actions to enhance efficiency.

(3) Reduce the cost of prescription drugs.

(4) Maximize the benefits of the Rx program and other governmental programs, including providing the benefits of the Rx program to other state program beneficiaries.

Sec. 6. The state department shall apply for any waiver of federal law, rule, or regulation necessary to implement this article.

Chapter 3. Requirements of Drug Manufacturers and Labelers

Sec. 1. (a) A drug manufacturer or labeler that sells prescription drugs in Indiana may voluntarily elect to provide prescription drug discounts by entering into a Rx rebate program established under this article with the state department.

(b) The rebate agreement voluntarily entered into under this chapter must require the manufacturer or labeler to make rebate payments to the state each calendar quarter according to a schedule established by the state department.

Sec. 2. (a) The state department shall negotiate the amount of the rebate voluntarily provided by a manufacturer or labeler in accordance with this chapter.

(b) When negotiating the amount of the rebate, the state department must consider the following:

(1) The rebate calculated under the federal Medicaid Rebate Program under 42 U.S.C. 1396r-8.

(2) The price provided to covered entities under 42 U.S.C. 256b.

(3) The national and state averages of all wholesale prices available or negotiated for prescription drugs.

(4) Any other information on prescription drug prices and price discounts.

(c) The state department and all other units of state government that pay for or acquire prescription drugs shall use their combined knowledge, information, data, and universal best efforts at the same time and same place to maximize the state's ability to obtain the maximum rebates possible.

Sec. 3. (a) The names of manufacturers and labelers that enter into rebate agreements established under IC 16-42.5-2-1 are public information, and the state department shall release this information to the public.

(b) The state department shall distribute to:

(1) physicians;

(2) pharmacists; and

(3) other health professionals;

information about the cost of prescription drugs produced by

manufacturers and labelers that enter into rebate agreements established under IC 16-42.5-2-1 and the cost of prescription drugs of manufacturers and labelers that have not entered into a rebate agreement.

Sec. 4. (a) For each manufacturer or labeler of prescription drugs that does not enter into a voluntary rebate agreement with the state department, the state department shall review the issue of the manner by which physicians dispense prescription drugs of the manufacturer or labeler under the prescription drug component of the state Medicaid program.

(b) The state department shall adopt rules under IC 4-22-2 to carry out this chapter.

Chapter 4. Calculation of Discount Price

Sec. 1. The state department shall establish discounted prices at which a retail pharmacy must offer prescription drugs covered by a rebate agreement and shall promote the use of effective and reduced cost drugs.

Sec. 2. (a) The state department shall use the following formula to compute the discount prices described in section 1 of this chapter:

STEP ONE: Determine the best average wholesale price.

STEP TWO: Add a designated dispensing fee that is at least the amount of the dispensing fee provided under the state Medicaid program.

(b) The state department shall use the following formula to compute the price at which a retail pharmacy must offer a prescription drug:

STEP ONE: Use the subsection (a) STEP TWO amount.

STEP TWO: Subtract the rebate paid by the state to a retail pharmacy.

Chapter 5. Sale of Prescription Drugs at Discounted Prices

Sec. 1. (a) A retail pharmacy may not charge more than the amount computed by the state department under IC 16-42.5-4-2(b) for drugs covered by the Rx program and sold to Rx program participants.

(b) The state department shall specify the discounted price levels.

(c) In determining the discounted price levels, the state department may consider an average of all rebates weighted by sales of drugs subject to these rebates over the most recent twelve (12) month period for which the information is available.

Chapter 6. Operation of the Rx Program

Sec. 1. (a) The Indiana board of pharmacy established by IC 25-26-13-3 shall adopt rules requiring disclosure by retail pharmacies to Rx program participants of the amount of savings provided by the Rx program.

(b) The rules adopted under subsection (a) must consider and protect information that is proprietary in nature.

Sec. 2. (a) A retail pharmacy shall submit claims to the state department to enable the state department to verify the amounts charged to Rx program participants.

(b) The state department may not impose transaction charges on retail pharmacies that submit claims or receive payments under the Rx program.

Sec. 3. (a) On a weekly or biweekly basis, the state department shall:

(1) reimburse a retail pharmacy for discounted prices provided to Rx program participants; and

(2) subject to IC 16-42.5-4-2(a), pay a retail pharmacy a dispensing fee set by the state department for each prescription dispensed by the retail pharmacy to Rx program participants.

(b) Unless a different amount is set by the state department under subsection (a) and subject to IC 16-42.5-4-2(a), the professional fee is three dollars ($3) per prescription.

Sec. 4. (a) The state department shall collect from each retail pharmacy utilization data necessary to calculate the amount of the rebate from a manufacturer or labeler, including statistics concerning the sale of prescription drugs to Rx program participants and other customers.

(b) The state department shall protect information that is confidential or proprietary in nature.

Chapter 7. Discrepancies in Rebate Amounts

Sec. 1. Discrepancies in rebate amounts must be resolved using the process established in this chapter.

Sec. 2. (a) If the manufacturer or labeler rebates less than the amount claimed by a retail pharmacy, resulting in a discrepancy that favors the manufacturer or labeler, the state department, at the state department's expense, may hire a mutually agreed upon independent auditor to conduct an audit to verify the accuracy of the data supplied by the manufacturer or labeler concerning the amount of the rebate.

(b) If a discrepancy exists following an audit by the independent auditor hired by the state department, the manufacturer or labeler shall justify the reason for the discrepancy or make payment to the state department for any additional rebate amount due.

Sec. 3. (a) If the manufacturer or labeler rebates more than the amount claimed by a retail pharmacy, resulting in a discrepancy against the interest of the manufacturer or labeler, the manufacturer or labeler, at the manufacturer's or labeler's expense, may hire a mutually agreed upon independent auditor to verify the accuracy of the data supplied to the state department regarding the manufacturer's or labeler's rebate amount.

(b) If a discrepancy exists following an audit by the independent auditor hired by the manufacturer or labeler, the state department shall justify the reason for the discrepancy or refund to the

manufacturer any excess rebate payment made by the manufacturer or labeler.

Sec. 4. Following the procedures established in sections 2 and 3 of this chapter, either the state department or the manufacturer or labeler may request a hearing under IC 4-21.5 if there is a dispute under this chapter.

Chapter 8. Rx Dedicated Fund

Sec. 1. As used in this chapter, "fund" refers to the Rx dedicated fund established by section 2 of this chapter.

Sec. 2. (a) The Rx dedicated fund is established. The fund consists of:

(1) revenue from manufacturers and labelers who pay rebates; and

(2) appropriations or allocations to the fund.

(b) The purpose of the fund is to reimburse retail pharmacies for discounted prices provided by the pharmacies to Rx program participants. The fund shall be administered by the state department.

(c) The expenses of administering the fund, including the following, shall be paid from money in the fund:

(1) Contracted services.

(2) Computer costs.

(3) Retail pharmacy dispensing fees.

(4) Other reasonable Rx program costs.

(d) The treasurer of state shall invest the money in the fund not currently needed to meet the obligations of the fund in the same manner as other public money may be invested. Interest that accrues from these investments shall be deposited in the fund.

(e) Money in the fund at the end of a state fiscal year does not revert to the state general fund.

Chapter 9. Terms of Rebate Agreement

Sec. 1. (a) A rebate agreement entered into under IC 16-42.5-3-1 must include a verification by the manufacturer or labeler that the price negotiated in the rebate agreement complies with this article.

(b) The state department may perform an audit of any manufacturer or labeler who has entered into a rebate agreement to determine whether the manufacturer or labeler complied with subsection (a). The state department may contract with an independent individual or organization to carry out the state department's duties under this subsection. A manufacturer or labeler shall provide information that the state department may reasonably require to enable it to determine whether the manufacturer or labeler is in compliance with this chapter.

(c) If the state department or its agent determines that a manufacturer or labeler has not complied with subsection (a), the state department shall require the manufacturer or labeler to do the following:

(1) Refund to the state department the difference between the

price offered to the state by the rebate agreement and the lowest price offered by the manufacturer or labeler as determined by the state department's negotiating formula under IC 16-42.5-3 and IC 16-42.5-4.

(2) Promptly pay the costs of the audit.

(d) The state may hire counsel to collect any amount, including attorney's fees and the cost of collection, under subsection (c) that is not promptly paid.

(e) The state department shall deposit any money collected under subsection (c) into the Rx dedicated fund.".

Page 152, between lines 20 and 21, begin a new paragraph and insert:

"SECTION 153. [EFFECTIVE JULY 1, 2002] **Recognizing that the state currently acts as a prescription benefits manager for a variety of health plans and assistance programs, IC 16-42.5 is enacted to cover new populations by expanding the state's role as a participant in the free marketplace as it relates to the prescription drug marketplace, just as health maintenance organizations and other large entities participate to negotiate voluntary rebates from drug companies, and use the funds to make prescription drugs more affordable to the state Medicaid program and to state residents. The intent of IC 16-42.5, as added by this act, is to improve public health and welfare, promote the economic strength of the state's citizens, and directly and indirectly benefit the state Medicaid program. IC 16-42.5 is enacted recognizing that the state government is the only agent that, as a practical matter, can be effective as a market participant on behalf of all the state's residents who are uninsured, underinsured, Medicaid participants, or taxpayers.**

SECTION 154. [EFFECTIVE JULY 1, 2002] **(a) As used in this SECTION, "office" refers to the office of Medicaid policy and planning established under IC 12-8-6-1.**

(b) Before September 1, 2002, the office shall apply to the United States Department of Health and Human Services for approval of any waiver necessary to develop a preferred drug formulary established in IC 12-15-35.5, as added by this act, and in accordance with 42 U.S.C. 1396r-8.

(c) The office may not implement the waiver until the office files an affidavit with the governor attesting that the federal waiver applied for under this SECTION is in effect. The office shall file the affidavit under this subsection not later than five (5) days after the office is notified that the waiver is approved.

(d) If the office receives a waiver under this SECTION from the United States Department of Health and Human Services and the governor receives the affidavit filed under subsection (c), the office shall implement the waiver not more than sixty (60) days after the governor receives the affidavit.".

Renumber all SECTIONS consecutively.

(Reference is to EHB 1004 as printed February 22, 2002.)

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Senator Antich